



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0072 6 JAN -3 P2:27

DEC 14 2005

Mr. Donald E. West
President
Gulf Biomedical Corporation
1218 Autrey Street
Suite 2
Houston, Texas 77006

Dear Mr. West:

This is in response to your letter of October 5, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Gulf Biomedical Corporation is making the claim "[T]he potency of the expensive erectile dysfunction drugs without the side effects..." for the product LoveMagic™.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product (i.e., it is an alternative to drugs intended for the treatment of erectile dysfunction, a disease) suggests that it is intended to treat, prevent, or mitigate disease, namely erectile dysfunction. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

97S 0163 LET 853

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'S. Walker', written in a cursive style.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Dallas District Office, Office of Compliance, HFR-SW140

GULF BIOMEDICAL CORPORATION

1218 AUTREY STREET

Suite 2

Houston, Texas 77006 0995 5 OCT 28 P2:16

Wednesday, October 05, 2005

OFFICE OF NUTRITIONAL PRODUCTS
LABELING AND DIETARY SUPPLEMENTS (HFS-810)
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
5100 PAINT BRANCH PARKWAY
COLLEGE PARK, MD 20740

OCT 17 2005

RE: NOTIFICATION OF STATEMENTS ON A DIETARY SUPPLEMENT KNOWN AS LOVEMAGIC TM

DEAR LADIES/GENTLEMEN:

PURSUANT OF 21 C.F.R. SUBPART F, SECTION 101.93, GULF BIOMEDICAL CORPORATION THE DISTRIBUTOR WHICH IS LOCATED AT 1216 AUTREY STREET #2, HOUSTON, TEXAS 77006 WISHES TO NOTIFY THE FOOD AND DRUG ADMINISTRATION THAT IT HAS COMMENCED MARKETING A DIETARY SUPPLEMENT KNOWN AS LOVEMAGIC TM WHICH CONTAINS STATEMENTS OF NUTRITIONAL SUPPORT IN ITS LABELING.

THE FOLLOWING STATEMENTS ARE BEING MADE FOR THE DIETARY SUPPLEMENT KNOWN AS LOVEMAGIC TM.

LOVEMAGIC TM - THE POTENCY OF THE EXPENSIVE ERECTILE DYSFUNCTION DRUGS WITHOUT THE SIDE EFFECTS (ADDRESSED BY THE INGREDIENTS VITAMIN B1 (THIAMINE MONONITRATE), VITAMIN B6 (PYRIDOXINE HCL), VITAMIN B12 (CYANOCOBALAMIN), PROPRIETARY BLEND (CONSISTING OF ELEUTHEROCOCCUS SENTICOSUS, GUARANA SEED POWDER, TRIBULUS TERRESTRIS POWDER AND KOREAN PANAX GINSENG OTHER INGREDIENTS: MAGNESIUM STEARATE, SILICA, GELATIN, GLYCERIN AND WATER). IN ACCORDANCE WITH THE ATTACHED LABEL COPY.

LOVEMAGIC TM HAS BEEN FORMULATED IN A SYNERGISTIC BALANCE OF HIGH QUALITY INGREDIENTS TO INSURE THE DESIRED EFFECT. THESE INGREDIENTS ARE WELL KNOWN FOR THEIR ABILITY TO PROVIDE ENERGY AND STAMINA. IN ACCORDANCE WITH THE ATTACHED LABEL.

THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE . GULF BIOMEDICAL CORPORATION MAINTAINS, ON FILE, THAT THESE STATEMENTS ARE TRUTHFUL AND NON-MISLEADING.

AN ORIGINAL AND TWO COPIES OF THIS NOTIFICATION ARE BEING SUBMITTED.

SINCERELY



DONALD E. WEST
PRESIDENT

ENCLOSURES: TWO COPIES OF THIS TWO PAGE LETTER W/ ATTACHMENTS

1473

Recommended Usage: Take one (1) capsule with water, 1 hour prior to desired effect.

LoveMagic™ has been formulated in a synergistic balance of high quality ingredients to insure the desired effect. These ingredients are well known for their ability to provide energy and stamina.**

**This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured for: Gulf Biomedical Corp.
1218 Aubrey St. #2
Houston, TX 77006



All Natural

LoveMagic™

"The potency of the expensive
erectile dysfunction drugs,
without the side effects..."

Dietary Supplement - 60 capsules

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 60

| Amount Per Serving | %DV |
|--|------------|
| Vitamin B1 (Thiamine mononitrate) | 1.5mg 100% |
| Vitamin B6 (Pyridoxine HCl) | 2mg 100% |
| Vitamin B12 (Cyanocobalamin) | 5mcg 50% |
| Ginseng (Panax 5/7 Saponin Extract) | 10mg |
| Proprietary Blend | 435mg |
| *Including: Eurythmum officinale, Eurythmum officinale powder, Tribulus terrestris powder and Korean Ginseng | |

*Daily values not established.

Other Ingredients: Magnesium stearate, silica, gelatin, glycerin and water.